



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,283	01/09/2001	Yuti Chernajovsky	0623.I000000/LLB/PAJ	5963

26111 7590 03/11/2003

STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
1100 NEW YORK AVENUE, N.W., SUITE 600  
WASHINGTON, DC 20005-3934

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/756,283	CHERNAJOVSKY ET AL.
<b>Examiner</b>	<b>Art Unit</b>	
Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 10 December 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-3,5-17,19-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 6-17,19-21,23 and 24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5,25 and 27 is/are rejected.
- 7) Claim(s) 26 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.

- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 10 December 2002 is acknowledged. Claims 1-3, 5-17, 19-21, and 23-27 are pending in this application. Claims 6-17, 19-21, 23, and 24 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.

3. The rejection of claims 1-5 and 18 under 35 U.S.C. 102(b) is withdrawn in response to Applicant's amendment limiting the claims to heterologous combinations.

4. The rejection of claims 1-5 and 18 under 35 U.S.C. 103(a) is withdrawn in response to Applicant's arguments.

5. The rejection of claims 1-5 and 18 under 35 U.S.C. 112, first paragraph, is withdrawn in response to Applicant's amendment.

6. The rejection of claims 1-5 and 18 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

#### ***New Grounds of Rejection***

7. Claims 1-3, 5, and 27 are newly rejected under 35 U.S.C. 103(a) as unpatentable over WO 91/08291.

Applicant has amended the claims to require heterologous fusion proteins. The specification does not disclose, nor does the prior art teach, any LAPs other than those that are associated with TGF $\beta$ . The definition of LAPs on p. 6 encompasses only precursor domains of TGFs  $\beta$ . For TGF $\beta$ , therefore, heterologous fusion proteins could only be LAPs for one TGF $\beta$

fused to another TGF $\beta$ . WO 91/08291 teaches that LAPs are produced as part of the precursor form of TGFs  $\beta$  (figure 1) and further teaches that LAPs can be used interchangeably among the various TGFs  $\beta$  on p. 24, lines 27-30. The WO 91/08291 patent fails to teach fusion proteins between TGFs  $\beta$  and heterologous LAPs. However, it would be *prima facie* obvious to one of ordinary skill in the art to generate such proteins. One of ordinary skill would be motivated to do so because WO 91/08291 teaches that LAPs are originally produced fused to TGF $\beta$  and that they are interchangeable, and one of ordinary skill would thus expect that a heterologous fusion protein would have the same characteristics as the naturally produced latent form of TGF $\beta$ .

8. New claim 27 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for methods using combinations of LAP with cytokines known to be useful for treatment of inflammatory disease, is not enabling for the use of all cytokines as broadly claimed.

The claim is drawn to a method of treating inflammatory conditions using LAP covalently linked to a cytokine. However, many cytokines, such as IFN $\gamma$ , IL-1, and TNF- $\alpha$ , are proinflammatory. Further, the art teaches that the effects of cytokines classed as anti-inflammatory are unpredictable. Opal et al. (Chest, 2000, vol. 117, pp. 1162-1172) teaches that anti-inflammatory cytokines have pro-inflammatory effects (p. 1162, column 2) and teaches that a supposedly pro-inflammatory cytokine, IL-6, acts predominantly as an anti-inflammatory cytokine (p. 1165, column 2). Opal et al. further teaches that anti-inflammatory agents can precipitate overwhelming infection (p. 1168, column 2). Thus, one of skill in the art could not predictably identify which cytokine-LAP fusions would be useful to treat inflammation. Without further guidance sufficient allow the skilled artisan to predict which fusion proteins could be

Art Unit: 1646

successfully used, it would require undue experimentation to practice Applicant's invention as broadly claimed.

9. New claim 25 is rejected under 35 U.S.C. 112, second paragraph, as indefinite. The claim recites "interferon". However, there are many interferons known in the art and the skilled artisan would not know which one was intended. Amendment of the claim to read "an interferon" would overcome this rejection.

10. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIMS 1-3, 5, 25, AND 27 ARE REJECTED. CLAIM 26 IS OBJECTED TO.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
March 5, 2003

*Yvonne Eyler*  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600